2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

The following policies provide the minimum procurement standards for an Organ Procurement Organization (OPO).

2.1 HOST OPO. The Organ Procurement Organization (OPO) responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining consent for the removal of organs, and organ allocation. Additionally, the Host OPO is responsible for ensuring that donor tissue typing information is entered into UNet^{SM} and that the approved OPTN organ allocation computer program is executed for each donor organ. Reasonable attempts shall be made to obtain a medical/behavioral history from individual(s) familiar with the donor. The Host OPO is responsible for organ procurement quality including appropriate preservation, and packaging of the organs, and assurance that adequate tissue typing material is procured, divided, and packaged. The Host OPO is responsible for ensuring that written documentation of donor evaluation, donor maintenance, consent for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials).

2.2 EVALUATION OF POTENTIAL DONORS. The Host OPO is responsible for performing the following activities and communicating this information to the OPO or transplant center for every donor:

2.2.1 Verifying that death has been pronounced according to applicable laws.

2.2.2 The Host OPO must perform the following evaluations and provide this information to the OPO or transplant center. The Host OPO must document in the donor record circumstances when such information is not available.

The Host OPO must determine whether there are conditions which may influence donor acceptance by:

Obtaining the donor's medical/behavioral history.

Reviewing the donor's medical chart.

Performing a physical examination of the donor.

Obtaining the donor's vital signs.

2.2.3 The Host OPO must perform the following pertinent FDA licensed, approved, or cleared serological screening tests and provide this information to the OPO or transplant center. In the event that such screening tests are not commercially available prior to transplant, then a FDA approved diagnostic test is permissible to assess the donor. The Host OPO must document in the donor record circumstances when such information is not available. In all cases, the transplant center will make the clinical decision whether to accept or reject the organ based on the available data or identify the need for additional information. The Host OPO may be requested to provide additional information if possible in addition to the information required on all donors. Required tests should include:

2.2.3.1 For all potential donors:

- ABO typing with sub-typing for ABO-A donors;
- FDA licensed Anti-HIV I, II;
- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- Anti-HTLV I/II;

- Anti-CMV;
- EBV serological testing;
- Blood and urine cultures;
- Urinalysis within 24 hours prior to cross clamp;
- Arterial blood gases;
- Chest x-ray; and
- Serum Glucose.

Additional Organ Specific information is required as follows:

2.2.3.2 For potential renal donors:
- Creatinine; and
- B.U.N.

2.2.3.3 For potential liver donors:
- AST;
- ALT;
- Alkaline phosphatase;
- Direct and total bilirubin
- INR (PT if INR not available); and
- PTT.

2.2.3.4 For potential heart donors:
- 12 Lead ECG; and
- Cardiology consult and/or echocardiogram.

2.2.3.5 For potential pancreas donors:
- Serum amylase.

2.2.3.6 For potential lung donors:
- Sputum gram stain.

2.3 DONOR MAINTENANCE. The Host OPO must make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or Transplant Center as follows:

2.3.1 Blood pressure is adequate to maintain perfusion of vital organs;

2.3.2 Vital signs are monitored;

2.3.3 I.V. therapy or drugs are administered as required (i.e. vasopressors, vasodilators; etc.);

2.3.4 Antibiotic therapy is administered as required; and

2.3.5 Intake and output.

2.4 OBTAINING CONSENT. The Host OPO must provide evidence of consent for donation according to applicable legal authority.

2.5 ORGAN PROCUREMENT QUALITY. Minimum standards of quality shall include documentation of the following:

2.5.1 All items in section 2.2.

2.5.2 Use of standard surgical techniques in a sterile operating environment.

2.5.3 Maintenance of flush solutions and preservation media at appropriate temperatures and recording of flush solutions and additives; organ anatomy, organ flush characteristics, flush solution amount and type, and organ abnormalities or surgical damage if any. The Host OPO is responsible for ensuring that the donor medications are given at appropriate times and that medication administration, including flush solutions and additives, is recorded during the retrieval process.

2.5.4 Each OPO, and their respective histocompatibility laboratory(s), will define and document the minimum tissue typing material required to generate match runs for local or regional placement of all organs. In view of the frequent need for regional shipment of pancreas and kidney allografts, however, sufficient specimens for several crossmatches are required. Minimal typing material to be obtained for EACH kidney and pancreas will include the following:

- One 7 to 10ml. clot (red top) tube for ABO verification, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm. wedge of spleen in culture medium, if available

For all other organs, the OPO will provide lymph nodes if requested and available.

2.5.5 Proper packaging of organs for transport (see Policy 5.0).

2.5.6 Properly packaged documentation containing complete donor information shall accompany each organ to the recipient transplant center.

2.5.6.1 Documentation accompanying each organ must include:

- ABO typing source documents;
- Serology results;
- Medical/Behavioral History form;
- Donor evaluation;
- Complete record of donor;
- Consent form; and
- Organ quality as described in section 2.5.

2.5.7 Complete information must be maintained by the Host OPO on any and all organs recovered. The Host OPO is responsible for ensuring that non-local procurement teams have transportation to and from the local airport.

2.6 INITIATING ORGAN PROCUREMENT AND PLACEMENT. In order to maximize the number of transplantable donor organs, tissue typing and crossmatching of an organ donor shall commence as soon as possible, ideally pre-procurement.

2.7 REMOVAL OF NON-RENAL ORGANS. When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. This policy also applies to non-renal organs from controlled donation after cardiac death (DCD) donors.

2.7.1 Multiple Abdominal Organ Procurement. It is expected that all authorized organs should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. The OPO will document the specific reason for non-recovery of an authorized organ. Cooperation between all organ recovery teams is required.

2.8 In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the standards of the DCD Model Elements as adopted in the OPTN Bylaws, Appendix B, Attachment III.

2. 9 MULTI-CULTURAL AND DIVERSITY ISSUES. Each OPO must develop and implement a plan to address a diverse population related to organ donation.